



## Complete Summary

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### GUIDELINE TITLE

Pediatric antiretroviral therapy.

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Pediatric antiretroviral therapy. New York (NY): New York State Department of Health; 2004. 24 p. [15 references]

### GUIDELINE STATUS

This is the current release of the guideline.

## \*\* REGULATORY ALERT \*\*

### FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released:

- On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm<sup>3</sup> unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the [FDA Web site](#) for more information.
- On June 10, 2005, Bristol-Myers Squibb and FDA notified healthcare professionals of revisions to the WARNINGS, PRECAUTIONS/Pregnancy and Information for Patients, and PATIENT INFORMATION sections of the prescribing information for Sustiva (efavirenz), indicated in the treatment of HIV-1 infection. The revisions are a result of four retrospective reports of neural tube defects in infants born to women with first trimester exposure to Sustiva, including three cases of meningomyelocele and one Dandy Walker Syndrome. As Sustiva may cause fetal harm when administered during the first trimester to a pregnant woman, pregnancy should be avoided in women receiving Sustiva. An antiretroviral pregnancy registry has been established to monitor fetal outcomes of pregnant women exposed to Sustiva. See the [FDA Web site](#) for more information.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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## SCOPE

### DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

### GUIDELINE CATEGORY

Evaluation

Management

Treatment

### CLINICAL SPECIALTY

Allergy and Immunology

Family Practice

Infectious Diseases

Pediatrics

### INTENDED USERS

Advanced Practice Nurses

Health Care Providers

Physician Assistants

Physicians

Public Health Departments

### GUIDELINE OBJECTIVE(S)

To develop guidelines for pediatric antiretroviral therapy

### TARGET POPULATION

Human immunodeficiency virus (HIV)-infected children and infants

### INTERVENTIONS AND PRACTICES CONSIDERED

## Assessment

1. Assessment of clinical and immunologic status, viral burden, resistance profile, and ability to adhere to an anti-retroviral (ARV) regimen.
2. Physical examination and history
3. Laboratory evaluations:
  - Complete blood count (CBC)
  - Kidney and hepatic function
  - Amylase, lipase, glucose, and lipid profile
  - Viral load (plasma human immunodeficiency virus [HIV]-1 ribonucleic acid [RNA] copy number)
  - Immunological status (CD4 count and percentage)
  - Genotypic/phenotypic resistance testing
4. Identification of potential barriers to treatment adherence

## Treatment/Management

1. Discussion of the risks and benefits of treatment with patients and their caregivers
2. Selection and initiation of antiretroviral therapy
  - First line regimes: zidovudine or stavudine plus lamivudine or didanosine plus nelfinavir or lopinavir/r or efavirenz
  - Other regimes: didanosine-EC or tenofovir plus lamivudine or emtricitabine plus efavirenz or atazanavir plus ritonavir or fosamprenavir (or amprenavir) plus ritonavir
  - Additional useful drugs: abacavir, nevirapine, saquinavir, indinavir, enfuvirtide
3. Follow-up monitoring
  - Monitoring for efficacy (repeat viral load and lymphocyte subsets)
  - Monitoring for toxicities and side effects (CBC, renal and hepatic function, amylase, lipase, glucose, lipid profile, lactic acid levels)
  - Monitoring adherence
4. Changing highly active antiretroviral (HAART) therapy if necessary
5. Salvage therapies

## MAJOR OUTCOMES CONSIDERED

- Prognostic utility of laboratory and clinical markers
- Efficacy of antiretroviral treatment (clinical status, immunological status, viral load)
- Safety of treatment
- Adverse effects of treatment (side effects, toxicities)

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

## NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review  
Review of Published Meta-Analyses

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3 to 4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Human immunodeficiency virus (HIV)-infected infants or children should be treated by pediatric HIV Specialists. When this is not possible, the treating clinician should seek consultation with a pediatric HIV Specialist (refer HIV Specialist Policy in the "Availability of Companion Documents" field).

The following clinical care issues are unique to HIV-infected children:

- Age-related differences in virologic, immunologic, and pharmacokinetic parameters
- Differences in tolerability and palatability of pediatric formulations of the medications
- Obstacles associated with adherence to complex regimens
- The dynamics of working with a family unit rather than a single individual

#### Assessment of the HIV-Infected Infant or Child Before Initiating Antiretroviral (ARV) Therapy

When a child is identified as HIV-infected, the clinician should begin an immediate assessment of the child's clinical and immunologic status, viral burden, resistance profile, and ability to adhere to an ARV regimen. This assessment should be repeated at least every 3 to 4 months to monitor for changes that may necessitate initiating ARV therapy or may affect a child's ability to receive or tolerate ARV therapy.

Before initiating therapy, clinicians should perform a comprehensive physical examination and should obtain a complete history and the following laboratory evaluations:

- Complete blood count (CBC)

- Assessment of kidney and hepatic function
- Amylase, lipase, glucose, and lipid profile (total cholesterol, high-density lipoprotein [HDL], low-density lipoprotein [LDL], and triglycerides)
- Viral load
- CD4 count and percentage
- Resistance profile

### Immunological Status

Clinicians should obtain an assessment of lymphocyte subsets (absolute count and percentage) for HIV-infected infants and children.

### Viral Load

Clinicians should obtain a baseline measurement of plasma HIV-1 ribonucleic acid (RNA) copy number (viral load) for all HIV-infected infants and children.

Clinicians should use one assay consistently in a patient because there is significant interassay variability.

### Genotypic/Phenotypic Resistance Testing

Clinicians should obtain resistance testing before initiating treatment in ARV-naïve infants, children, and adolescents or changing a failing regimen for patients already receiving treatment.

Clinicians should consult with an expert for interpretation of resistance testing results.

### Potential Barriers to Treatment Adherence

Clinicians should identify and address potential barriers to adherence with caregivers and patients before initiating a regimen.

The clinician should discuss the importance of consistent adherence to the ARV regimen with the child in an age-appropriate way.

If adherence barriers cannot be overcome, the clinician and family may choose to defer treatment.

The following potential barriers should be assessed and addressed before initiating ARV therapy:

- Communication difficulties due to language, literacy, or differing beliefs
- Unstable living conditions (lack of housing, food, childcare)
- Discomfort with disclosure of HIV status
- Inadequate education about disease and medications
- Challenges regarding access to health care
- Medical, psychiatric, psychological, or cognitive limitations of the caregiver or child
- Foster care/consent

- Potential interference with activities of daily living, especially school, meals, etc.

### Deciding When to Initiate ARV Therapy

The clinician should discuss the risks and benefits of a treatment regimen with HIV-infected children and their caregivers, allowing them to make an informed decision regarding initiating therapy. If the potential risks outweigh the benefits, the clinician and family may choose to defer treatment.

In most cases, clinicians should initiate treatment soon after HIV infection is identified in an infant, either immediately or as soon as the resistance profile is available.

Clinicians should initiate treatment in children older than 1 year of age with symptomatic disease or advancing immunosuppression.

### Indications for Initiating ARV Therapy in HIV-infected Children $\geq 1$ Year of Age

Clinical Category	CD4 Percentage	Plasma HIV RNA Copy Number	Recommendation
AIDS (Clinical category C)* OR	<15% (Immune category 3)*	Any value	Initiate ARV therapy
Mild-moderate symptoms (Clinical category A or B)* OR	15-25%** (Immune category 2)* OR	>100,000 copies/mL** *	Consider initiating ARV therapy
Asymptomatic (Clinical category N)* AND	>25% (Immune category 1)* AND	<100,000 copies/mL** *	Many experts would defer therapy and closely monitor clinical, immune, and viral parameters for deterioration

Modified from the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection developed by The Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children convened by the National Pediatric and Family HIV Resource Center (NPHRC), The Health Resources and Services Administration (HRSA), and The National Institutes of Health (NIH). June 25, 2003.

\* See Appendix A in the original guideline document

\*\* Many experts would initiate therapy if CD4 cell percentage is between 15 and 20% and defer therapy with increased monitoring frequency in children with CD4 cell percentage 21 to 25%.

\*\*\*There is controversy among pediatric HIV experts regarding the plasma HIV RNA threshold warranting consideration of therapy in children in the absence of clinical or immune abnormalities; some experts would consider initiation of therapy in asymptomatic children if plasma HIV RNA levels were between 50,000 to 100,000 copies/mL.

### Initiating and Selecting an ARV Regimen

ARV treatment should be initiated and/or changed by a pediatric HIV Specialist who is experienced with the issues that distinguish pediatric patients from adults (see HIV Specialist Policy in the "Availability of Companion Documents" field).

Clinicians should obtain a maternal and infant (or child) ARV treatment history and should assess the resistance profile in the context of the ARV history before choosing a regimen.

The clinician should initiate an ARV regimen of at least three drugs, including two nucleoside reverse transcriptase inhibitors (NRTIs) in combination with a protease inhibitor (PI) or a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Refer to the original guideline documentation for recommended regimens (Table 4) and for formulations and dosages for each drug (Appendix C).

Key Point: Many of the newer US Food and Drug Administration (FDA)-approved ARV drugs have been released on the market without specific pediatric formulations; however, pediatric clinicians should still consider using these drugs as part of their armamentarium after consulting with a pediatric HIV Specialist.

Key Point: In HIV-infected children, especially infants, drug-drug interactions and pharmacokinetic parameters related to age/developmental stage should be considered when selecting components of the treatment regimen. In some children, the doses may exceed those recommended for HIV-infected adults.

## Drug-related Considerations when Choosing an ARV Regimen

### Ease of Administration:

- Availability and palatability of a pediatric formulation
- Patient's ability to swallow pills/soft gel caps
- Frequency of dosing (once a day [qd], twice a day [bid], three times a day [tid], four times a day [qid])
- Food effects
- Storage requirements (e.g., refrigeration)

### Safety and Efficacy:

- Age-related pharmacokinetics
- Efficacy of therapeutic regimen
- Durability of antiretroviral effect
- Drug interactions
- Adverse reactions
- Safety in pregnancy (for female adolescents)
- Likelihood of resistance

## Follow-Up Monitoring for Patients Receiving ARV Therapy

Children receiving highly active antiretroviral therapy (HAART) should be followed by a pediatric HIV Specialist either as their primary care clinician or through consultation with their primary care clinician.



Clinicians should either contact patients/caregivers by phone or arrange to see them in person 1 to 2 weeks after initiating therapy to monitor adherence and assess for side effects.

### Monitoring for Efficacy

Clinicians should obtain a repeat viral load within 4 to 6 weeks after initiating or changing ARV therapy. If there is no decrease in viral load, adherence should be reviewed.

Clinicians should routinely obtain lymphocyte subsets and viral load every 3 to 4 months. Children with significant ongoing viral replication may require more frequent monitoring.

Clinicians should repeat all tests that suggest a significant change (either positive or negative) in plasma RNA copy numbers.

**Key Point:** The goal of ARV therapy should be an undetectable plasma viral load, which is defined as <400 copies/mL or <40 to 50 copies/mL (with ultrasensitive assay). If this is not achievable, realistic expectations of available therapy should dictate an acceptable level of viremia for each child.

### Monitoring for Toxicities and Side Effects

Clinicians should perform a history, physical examination, and laboratory monitoring for toxicity within 4 weeks after initiating ARV therapy and should repeat these at least every 3 months in children receiving ARV therapy.

Laboratory assessments for toxicity should include CBC, assessment of renal and hepatic function, amylase, lipase, and glucose.

When nevirapine is initiated, the clinician should obtain serum liver enzymes every 2 weeks until 6 weeks after initiating therapy, and then monthly for 3 to 4 months.

Screening of serum cholesterol, triglycerides, low-density lipoprotein, and high-density lipoprotein should be performed in HIV-infected children initiating HAART, 3 to 6 months after initiation and approximately every 6 months thereafter. Abnormal results warrant repeat studies performed in the fasting state.

Clinicians should assess lactic acid levels in patients receiving nucleoside reverse transcriptase inhibitors (NRTIs) who develop clinical manifestations (abdominal pain, anorexia, nausea/vomiting, hyperventilation, and/or myalgias) or laboratory markers suggestive of lactic acidosis.

**Key Point:** Although some adverse events do not warrant stopping therapy, others, such as a hypersensitivity reaction to abacavir or hepatitis associated with nevirapine, require prompt recognition of symptoms and permanent interruption of the drug. Failure to recognize these symptoms may lead to death.

### Monitoring Adherence

The clinician should regularly discuss the importance of consistent adherence to the ARV regimen with the caregiver and the child in an age-appropriate way.

At each visit, clinicians should assess adherence in children and adolescents receiving ARV therapy. In cases in which adherence becomes problematic and cannot be resolved, simplification or discontinuation of therapy should be included as a potential management strategy.

Key Point: Challenges of adherence change as HIV-infected children age and enter different developmental stages.

### Changing HAART Regimen

Decisions regarding changing therapy should be individualized and should be made in consultation with a pediatric HIV Specialist.

The clinician should decide whether to change therapy, or modify or continue the present regimen in any of the following circumstances:

- Clinical progression
- Sustained increase in viral load
- Progressive immunodeficiency
- Significant toxicity
- Significant unmodifiable adherence issues have developed with the current regimen

When new regimens are selected because of virologic failure, the clinician should perform resistance testing while the child is still on the failing regimen (see "Genotypic/Phenotypic Resistance Testing" section).

When the regimen is changed because of virologic failure, clinicians should switch all drugs at the same time. Ideally, the new regimen should have three new active drugs that the child has not previously taken and that are not cross-resistant to medications the child has taken.

The clinician should discuss the risks and benefits of the specific medications under consideration with the family and child when changing treatment.

Key Point: When virologic suppression has been achieved but therapy needs to be changed because of toxicity, one drug may be substituted for another provided that the new drug is of equal potency.

Considerations when deciding whether to change therapy:

- Previous ARV therapy and resistance profile
- Likelihood of adherence (see "The Importance of Treatment Adherence" section)
- Clinical and immunologic status
- The child's ability to take and tolerate the medications
- The likelihood of achieving complete viral suppression
- The possibility of toxicities or drug-drug interactions.

## PI- and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)-Experienced Children: Salvage Therapies

The choice of salvage therapy in PI- and NNRTI-experienced children should be made on a case-by-case basis and should be guided by the child's ARV history, resistance profile, and ability to adhere to a regimen.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

#### General Benefits

Appropriate evaluation and management of human immunodeficiency virus (HIV)-infected children and infants

#### Specific Benefits

- Effective early treatment allows normal immune maturation or preservation of immune function and better growth and development.
- Early initiation of therapy can lead to prolonged virologic suppression, immune preservation, clinical stability, and normal growth velocity and cognitive development.
- Numerous studies show that children who are adherent to highly active antiretroviral therapy (HAART) can achieve suppression of viral replication to below detectable levels and can gain concurrent clinical and immunologic benefit.
- There is evidence suggesting that patients who respond only partially to antiretroviral (ARV) therapy can still gain clinical and immunologic benefit even when complete viral suppression is not achieved. Prolonged viral suppression can prevent or delay the development of ARV-resistant mutations.

### POTENTIAL HARMS

#### Toxicities, Side Effects, and Drug Interactions of antiretroviral (ARV) Therapy

- Abacavir can lead to a hypersensitivity reaction that can be fatal upon rechallenge.

- Nevirapine is associated with hepatitis
- Nucleoside reverse transcriptase inhibitors (NRTIs) may cause lactic acidosis. Fatal lactic acidemia reported in two pregnant women receiving NRTI therapy with stavudine and didanosine may indicate that women, especially during pregnancy, have a greater risk.
- Short- and long-term toxicities of ARV therapy include abnormal fat distribution, hyperlipidemia, mitochondrial toxicity, hypersensitivity reactions, peripheral neuropathy, liver toxicity, diabetes, renal toxicity, anemia, neutropenia, pancreatitis, and diarrhea.
- To avoid reduction of atazanavir absorption, atazanavir should not be given within 30 minutes of didanosine

## CONTRAINDICATIONS

### CONTRAINDICATIONS

- Zidovudine and stavudine should never be given together
- Efavirenz is not yet approved for children under 3 years.
- Tenofovir, emtricitabine, and atazanavir are not yet approved for children under 18 years.
- Amprenavir oral solution should not be given to children under 4 years.
- Saquinavir and indinavir are not yet approved for children under 13 years.
- Enfuvirtide is not yet approved for children under 6 years.
- Saquinavir hard-gel capsules should never be given without ritonavir.
- Delavirdine and zalcitabine are not approved for children and do not offer anything that warrants their off-label use except in the most unusual circumstances. They should rarely if ever be used in children.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers).

- Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
  - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
  - What steps need to be taken to make these activities happen?
  - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
  - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
  - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
  - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
  - Did the processes and strategies work? Were the guidelines implemented?
  - What could be improved in future endeavors?

## IMPLEMENTATION TOOLS

### Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Pediatric antiretroviral therapy. New York (NY): New York State Department of Health; 2004. 24 p. [15 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

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#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### GUIDELINE STATUS

This is the current release of the guideline.

#### GUIDELINE AVAILABILITY

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

#### AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Pediatric antiretroviral therapy. Tables and recommendations. New York (NY): New York State Department of Health; 2004 Jun. 17 p. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).
- HIV specialist policy. New York (NY): New York State Department of Health; 2003 Mar. Electronic copies: Available in Portable Document Format (PDF) from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

#### PATIENT RESOURCES

None available

#### NGC STATUS

This NGC summary was completed by ECRI on January 13, 2005. This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on Sustiva (efavirenz).

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